

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

INSEP 50 (Capsule)

INSEP 100 (Capsule)

INSEP 150 (Capsule)

INSEP 200 (Capsule)

Fluconazole

Read all of this leaflet carefully before you start taking **INSEP**.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **INSEP** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT **INSEP** CONTAINS

The active substance is Fluconazole.

INSEP 50

Each capsule contains 50 mg fluconazole.

INSEP 100

Each capsule contains 100 mg fluconazole.

INSEP 150

Each capsule contains 150 mg fluconazole.

INSEP 200

Each capsule contains 200 mg fluconazole.

The other ingredients of **INSEP** are lactose monohydrate, maize starch, sodium lauryl sulphate, silica, colloidal anhydrous and magnesium stearate. The empty hard gelatin capsule shell consists of gelatin, sodium lauryl sulfate and titanium dioxide (C.I. No: 77891). The capsules are printed with edible ink,

shellac and yellow iron oxide (C.I. No: 77492).

2. WHAT INSEP IS USED FOR

INSEP is used to treat serious fungal infections that may occur in different parts of the body.

3. BEFORE YOU TAKE INSEP

Do not take INSEP:

- If you have a known hypersensitivity (allergy) to fluconazole or to any of the ingredients of **INSEP** or to related azole compounds.
- If you are taking medicines such as cisapride, astemizole, pimozide and quinidine as these medicines may prolong the QT interval and may cause irregular heart beats.
- If you are pregnant.
- If you are breastfeeding your baby.

Take special care with INSEP:

- You will be closely monitored by your doctor if you have an underlying liver disease.
- The dose of **INSEP** must be adjusted if you have kidney problems.
- If you develop rashes including blisters or pink to red symmetrically arranged blotches that are itchy, stop taking **INSEP** and contact your doctor immediately.

Pregnancy and Breastfeeding:

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **INSEP**.

You should not take **INSEP** if you are pregnant, planning to become pregnant or breast-feeding your baby.

Driving and using machinery:

INSEP may cause problems with your vision. If affected do not drive or operate machinery.

Important information about some of the ingredients of INSEP:

INSEP contains lactose, which is a type of sugar. So before taking **INSEP**, please consult your doctor for advice if you have an intolerance to some sugars.

Taking other medicines with INSEP:

INSEP interacts with warfarin (medicines that thin the blood to prevent blood clots), short acting benzodiazepines (midazolam, triazolam or similar medicines used to help you sleep), ciclosporin, tacrolimus (to prevent transplant rejection) phenytoin, theophylline (used to control asthma), zidovudine (used to treat HIV-infection), cisapride (used for stomach upsets) and rifabutin (antibiotics for infections).

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO TAKE INSEP

Do not share medicines prescribed for you with any other person.

Always take **INSEP** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **INSEP** is too strong or too weak, talk to your doctor or pharmacist.

The duration of treatment and dosage depends on the severity of the infection, clinical response and bacteriological cultures.

In adults, the dosage range is 50 mg – 400 mg daily.

INSEP is not suitable for children.

If you take more INSEP than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take INSEP:

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

INSEP can have side effects.

Not all side effects reported for **INSEP** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **INSEP**, please consult your doctor, pharmacist or other healthcare professional for advice.

Contact your doctor **IMMEDIATELY** if you experience any of the following side-effects:

A sudden life-threatening allergic reaction, rapid swelling of the skin of your face, yellow discolouration of your skin and eyes, dark urine, red blotchy rash and blisters in your mouth or nose.

If you experience any of these side-effects, you should immediately stop taking **INSEP**.

Contact your doctor **AS SOON AS POSSIBLE** if you notice any of the following side-effects:

Abdominal pain, diarrhoea, flatulence, nausea, vomiting, changes in the way food tastes (taste perversion), fever, frequent infections, bruising, nose bleeds, itchy skin, hair loss, seizures (fits), constipation, menstrual disorders and abnormal vision.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF INSEP

Store all medicines out of reach of children.

1. Blister:

Store at or below 25 °C. Keep blisters in the original carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

2. HDPE Container:

Store at or below 25 °C. Keep well closed.

KEEP OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF INSEP

INSEP 50:

1) Pack size: 14's Blister Pack

Capsules are packed in clear 250 micron PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer.

Each carton contains 1 blister of 14 capsules each.

2) Pack size: 30's HDPE Container Pack

Capsules are packed in a 40 ml white opaque HDPE container with a white opaque polypropylene stock ribbed closure with induction seal wad.

Each container contains 30 capsules.

INSEP 100:

1) Pack size: 30's Blister Pack

Capsules are packed in clear 250 micron PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer.

Each carton contains 3 blisters of 10 capsules each.

2) Pack size: 30's HDPE Container Pack

Capsules are packed in a 40 ml white opaque HDPE container with a white opaque polypropylene stock ribbed closure with induction seal wad.

Each container contains 30 capsules.

INSEP 150:

1) Pack size: 1's Blister Pack

Capsules are packed in clear 250 micron PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer.

Each carton contains 1 blister of 1 capsule each.

2) Pack size: 4's Blister Pack

Capsules are packed in clear 250 micron PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer.

Each carton contains 1 blister of 4 capsules each.

INSEP 200:

1) Pack size: 30's Blister Pack

Capsules are packed in clear 250 micron PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer.

Each carton contains 3 blisters of 10 capsules each.

2) Pack size: 30's HDPE Container Pack

Capsules are packed in a 60 ml white opaque HDPE container with a white opaque polypropylene stock ribbed closure with induction seal wad.

Each container contains 30 capsules.

8. IDENTIFICATION OF INSEP

INSEP 50:

White to off-white opaque/white to off-white opaque size '4' hard gelatin capsule filled with white to off-white powder and imprinted with 'E' on white to off-white opaque cap and '95' on white to off-white opaque body with yellow ink.

INSEP 100:

White to off-white opaque/white to off-white opaque size '2' hard gelatin capsule filled with white to off-white powder and imprinted with 'E' on white to off-white opaque cap and '96' on white to off-white opaque body with yellow ink.

INSEP 150:

White to off-white opaque/white to off-white opaque size '1' hard gelatin capsule filled with white to off-white powder and imprinted with 'E' on white to off-white opaque cap and '97' on white to off-white opaque body with yellow ink.

INSEP 200:

White to off-white opaque/white to off-white opaque size '0' hard gelatin capsule filled with white to off-white powder and imprinted with 'E' on white to off-white opaque cap and '98' on white to off-white opaque body

with yellow ink.

9. REGISTRATION NUMBER/REFERENCE NUMBER

INSEP 50: 43/20.2.2/0566

INSEP 100: 43/20.2.2/0567

INSEP 150: 43/20.2.2/0568

INSEP 200: 43/20.2.2/0569

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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